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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,499	07/15/2005	Mamoru Kobayashi	Q89144	5259

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EXAMINER	
ZAREK, PAUL E	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
02/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,499	KOBAYASHI ET AL.	
	Examiner	Art Unit	
	Paul Zarek	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 7-14 have been added, and Claims 1-6 have been cancelled by the Applicant in correspondence filed on 12/04/2008. Claims 1-6 are currently pending. This is the second Office Action on the merits of the claim(s).

Priority

2. Applicant's claim for the benefit of a prior-filed international application PCT/JP04/00355 (filed on 01/19/2004) under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. The effective filing date of the instant application is 01/19/2004.

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) to Japan Application 2003-12947 (filed on 01/22/2003). The foreign priority date of the instant application is 01/22/2003.

RESPONSE TO ARGUMENTS

4. Claims 1-6 were rejected under 35 U.S.C. 112, first paragraph, as not being fully enabled by the instant specification. This rejection is moot in light of Applicants' cancellation of Claims 1-6.

5. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Yanagi, et al., (Chem. Pharm. Bull, 2001). This rejection is moot in light of Applicants' cancellation of Claims 1-6.

6. Newly entered Claims 7-14 are examined on their merits and the following **FINAL** rejection is made.

Claim Rejections - 35 USC § 112 (2nd paragraph)

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

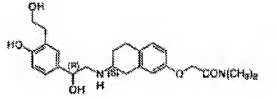
8. Claims 7-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejected claims are drawn to a method of treating gestational toxicosis or improving intrauterine growth retardation (IUGR) comprising administration of a phenylethanolaminotetralin derivative, or salt thereof. The method claims do not disclose a subject to be treated. The claims are considered indefinite, because it is unclear just who the subject would be. Amending the claims to include the limitation "to a subject in need of such treatment," would overcome this rejection.

9. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 recites the limitation "the disease to be treated is hyperlipidemia associated with gestational toxicosis" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Claim 14 depends upon Claim 7, which is drawn to a method of treating gestational toxicosis, not a disease associated with gestational toxicosis.

Claim Rejections - 35 USC § 103

10. Claims 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobayashi, et al. (The Journal of Pharmacology and Experimental Therapeutics, 2001, already of record).

11. Claims 7 and 8 of the instant application is drawn to a method of treating gestational toxicosis (e.g. preeclampsia, Claim 7) or IUGR (Claim 8) comprising administration of the phenylethanolaminotetralin derivative,



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or a pharmaceutically acceptable salt thereof. Claims 9 and 10 limit Claims 7 and 8, respectively, to the H_2SO_4 salt of the phenylethanolaminotetralin derivative. Claims 11-13 limit Claims 8-10, respectively, to treat asymmetrical IUGR. Claim 14 limit the disease to be treated to be hyperlipidemia associated with gestational toxicosis.

12. Kobayashi, et al., teach that the H_2SO_4 salt of the claimed compound (hereafter KUR-1246) is a potent and selective uterine relaxant (abstract). KUR-1246 is more selective for the myometrium without increasing atrial heart rate or inhibiting spontaneous contraction of the proximal colon (Table 3). *In vivo*, KUR-1246 selectively inhibited uterine contractions in pregnant rats, and "shows treat potential as a drug for the treatment of preterm labor in humans"

(pg 671, col 1, paragraph 4, ending on col 2). Kobayashi, et al., do not specifically contemplate preeclampsia (gestational toxicosis) or IUGR.

13. Preeclampsia and IUGR are commonly treated with bed rest, or, pharmacologically, with β2-adrenoceptor agonists, such as ritodrine and terbutaline. Such treatments increase bloodflow to the fetus by inhibiting the contractions of uterine smooth muscle. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to administer KUR-1246, a known specific uterine relaxant, to a subject suffering preeclampsia or IUGR. Hyperlipidemia is a common complication of preeclampsia. Therefore, treating preeclampsia would necessarily treat hyperlipidemia associated with gestational toxicosis.

Conclusion

14. Claims 7-14 are rejected.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/Rita J. Desai/
Primary Examiner, Art Unit 1625